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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,243	12/22/2005	Clara Lucia Garcia-Rodenas	112701-694	6067

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K&L Gates LLP
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EXAMINER	
GANGLE, BRIAN J	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
04/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,243	GARCIA-RODENAS ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *1-10,12,13,15,16,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 17-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and remarks, filed on 1/23/2009, are acknowledged. Claims 11 and 17-18 are amended. Claim 14 is cancelled. Claims 1-13 and 15-20 are pending. Claims 1-10, 12-13, 15-16, and 19-20 are withdrawn as being drawn to non-elected inventions. Claims 11 and 17-18 are currently under examination.

Objections Withdrawn

The objection to the specification for the use of the trademarks ARASCO and DHASCO is withdrawn in light of applicant's amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "a combination of at least one substance selected from the group consisting of specific fats or non-digestible oligosaccharides, associated with a microorganism," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "comprising the steps of further ensuring an optimal barrier function in infants," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the phrase "comprising the steps of further reducing the risk of developing allergy and infection," is withdrawn in light of applicant's amendment thereto.

Claim Rejections Maintained

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Haschke *et al.* (WO 01/64225 A1, 2001), is maintained for the reasons set forth in the previous office action.

Applicant argues:

1. That applicant has surprisingly found that gut barrier function or gastrointestinal health may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. Applicant asserts that the microorganisms of the claims differ in their ability to survive in the different parts of the gastro-intestinal tract and can be incorporated into a cocktail with bioactive ingredients that reinforce their effects by stimulating the maturation of barrier mechanisms. Applicant asserts that the microorganisms of the present invention are designed to release the specific bioactive ingredients at a certain location of the gut depending on the sort of pretreatment undergone by the microorganism.

2. That Haschke *et al.* fail to disclose or suggest a method comprising the step of administering a composition to an infant inducing a pattern of gut barrier maturation similar to that observed in breast-feeding. Applicant asserts that the "combination of the specific claimed bioactive ingredients and at least one microorganism recited in the present claims provides a specific effect not taught or suggested by the cited references."

3. That anticipation requires the presence in a single prior art disclosure of each and every element of the claimed invention. Applicant asserts that the reference does not disclose a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding and thus does not disclose each and every element of the claimed invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the claims lack any mention of particular organisms that are designed to release specific bioactive ingredients in specific locations of the gut. What is required by the claims is administration of a combination of fats or non-digestible oligosaccharides and at least one microorganism. This is exactly what is taught by Haschke *et al.* Furthermore, it was not applicant that discovered that these compositions can improve gastrointestinal health. As evidenced by the teachings of Haschke *et al.* and Giffard *et al.*, this was known prior to applicant's invention.

Regarding arguments 2 and 3, the instant specification describes numerous organisms and numerous fats and non-digestible oligosaccharides that are acceptable for the instant invention. Haschke *et al.* teaches the use of these. Therefore, unless applicant is asserting that the claims lack appropriate written description and are not fully enabled, one of skill in the art would have no choice but to believe that administration of the same composition (fats and non-digestible oligosaccharides in combination with at least one microorganism) would lead to the same results (maturation of the gut barrier similar to that observed in breast-feeding). Although Haschke *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and this would necessarily lead to maturation of the gut barrier similar to that observed in breast-feeding. Whether or not Haschke *et al.* recognized this fact is immaterial as merely discovering and claiming a new benefit of an old process cannot render the process again patentable.

As outlined previously, the instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with a microorganism to an infant (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Haschke *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, non-digestible oligosaccharides, and specific fats (see page 6, lines 10-20; page 5, lines 1-5; page 4, lines 15-25). Although Haschke *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known

invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the disclosure of Haschke *et al*. anticipates the instant claims.

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Giffard *et al.* (WO 03/041512 A1, 5/2003), is maintained for the reasons set forth in the previous office action.

Applicant argues:

1. That applicant has surprisingly found that gut barrier function or gastrointestinal health may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. Applicant asserts that the microorganisms of the claims differ in their ability to survive in the different parts of the gastro-intestinal tract and can be incorporated into a cocktail with bioactive ingredients that reinforce their effects by stimulating the maturation of barrier mechanisms. Applicant asserts that the microorganisms of the present invention are designed to release the specific bioactive ingredients at a certain location of the gut depending on the sort of pretreatment undergone by the microorganism.

2. That Giffard *et al.* fail to disclose or suggest a method comprising the step of administering a composition to an infant inducing a pattern of gut barrier maturation similar to that observed in breast-feeding. Applicant asserts that the "combination of the specific claimed bioactive ingredients and at least one microorganism recited in the present claims provides a specific effect not taught or suggested by the cited references."

3. That anticipation requires the presence in a single prior art disclosure of each and every element of the claimed invention. Applicant asserts that the reference does not disclose a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding and thus does not disclose each and every element of the claimed invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the claims lack any mention of particular organisms that are designed to release specific bioactive ingredients in specific locations of the gut. What is required by the claims is administration of a combination of fats or non-digestible oligosaccharides and at least one microorganism. This is exactly what is taught by Giffard *et al.*

Furthermore, it was not applicant that discovered that these compositions can improve gastrointestinal health. As evidenced by the teachings of Haschke *et al.* and Giffard *et al.*, this was known prior to applicant's invention.

Regarding arguments 2 and 3, the instant specification describes numerous organisms and numerous fats and non-digestible oligosaccharides that are acceptable for the instant invention. Giffard *et al.* teaches the use of these. Therefore, unless applicant is asserting that the claims lack appropriate written description and are not fully enabled, one of skill in the art would have no choice but to believe that administration of the same composition (fats and non-digestible oligosaccharides in combination with at least one microorganism) would lead to the same results (maturation of the gut barrier similar to that observed in breast-feeding). Although Giffard *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and this would necessarily lead to maturation of the gut barrier similar to that observed in breast-feeding. Whether or not Giffard *et al.* recognized this fact is immaterial as merely discovering and claiming a new benefit of an old process cannot render the process again patentable.

As outlined previously, the instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with a microorganism to an infant (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Giffard *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, prebiotic (non-digestible oligosaccharides), and specific fats (see page 19, lines 1-20; page 18, lines 5-10; page 8, lines 15-25; page 7, lines 25-30). Although Giffard *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The

mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the disclosure of Giffard *et al.* anticipates the instant claims.

New Claim Rejections

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rendered vague and indefinite by the phrase "further comprising the step of ensuring an optimal barrier function in infants." Neither the claims nor the specification provides any means of accomplishing this "step" or determining if it has been accomplished. Furthermore, it is not clear what the goal of this step is. It is not clear whether this limitation is meant to be a step of evaluating the results of the administration of the product, or is it a step where further steps are taken so that optimal barrier function is attained. In addition, the use of the word "an" implies there are multiple barrier functions and that only one needs to be optimized. Therefore, it is not clear what barrier function is to be optimized or how this is to be accomplished.

Applicant argues:

1. That the specification describes how a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria. Applicant discusses the fact that maturation of the barrier is faster in breast-fed infants than in formula-fed infants and that this may explain the higher prevalence of allergy and infection. Applicant refers to the Example 1, where rats who consumed the compositions of the present invention were found to have restored intestinal permeability to proteins and other

macromolecules and state that this illustrates how the method works to ensure an optimal barrier function in rats.

2. That the word "an" is not placed in front of the phrase "optimal barrier function" to imply that there are multiple barrier functions, but so as to have proper antecedent basis.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant's arguments do not address the issues raised in the rejection. It appears, from applicant's arguments, that there is no further step necessary to ensure an optimal barrier function, as the step of administering the composition accomplishes this. Therefore, it is not clear what further step is required by claim 17.

Regarding argument 2, while antecedent basis is necessary for the terms in the claims, applicant's arguments are not part of the claims. The claim contains the word "an" which implies that there are multiple barrier functions. It is not clear from the claim which barrier function is meant to be optimized or how this is to be accomplished.

Claim 18 is rendered vague and indefinite by the phrase "further comprising the step of reducing the risk of developing allergy and infection." Neither the claims nor the specification provides any means of accomplishing this "step."

Applicant argues:

1. That the specification describes how a newborn intestine experiences a process of maturation that ends by the establishment of a functional barrier to macromolecules and pathogenic bacteria. Applicant discusses the fact that maturation of the barrier is faster in breast-fed infants than in formula-fed infants and that this may explain the higher prevalence of allergy and infection. Applicant asserts that the action of the administered composition reduces the susceptibility to allergy and infection.

Applicant's arguments have been fully considered and deemed non-persuasive.

Applicant's arguments do not address the issues raised in the rejection. First, it appears, from applicant's arguments, that there is no further step necessary to reduce the risk of developing allergy and infection, as the step of administering the composition accomplishes this. Therefore, it is not clear what further step is required by claim 18.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645